REMARKS

Claims 1-3, 5-8, and 10-16 are pending in the subject application upon entry of the amendments. Claims 1-3, 5, 6, 11, 12, and 14 have been amended to disclaim the cited art. Claims 10 and 11 have been amended for consistency with the amendments to claim 1. Clams 4, 9, and 17-21 have been canceled without prejudice or disclaimer and to expedite allowance of the application. Favorable reconsideration in light of the amendments and the remarks which follow is respectfully requested.

Indefiniteness Rejection

Claims 1-21 stand rejected under 35 U.S.C. § 112, second paragraph, because, according to the Office Action, the terms "nanometer," granules," "low," and "atomizated" are not clear. Claims have been amended to more clearly define the subject matter of certain aspects of the invention so that one skilled in the art can readily understand the metes and bounds thereof.

Claim 11 stands rejected under 35 U.S.C. § 112, second paragraph, with regard to the term "PVP K_{30}". The term "PVP K_{30}" refers to a well-known product of polyvinylpyrrolidone having a K value of 27-32 (CAS No.: 9003-39-8), which is commercially available. Moreover, the same term was examined and found clear in issued patents, for example, Patent Nos. 5,681,586 and 5,587,191. The term is therefore clear and understandable to one skilled in the art.

In view of the foregoing, withdrawal of the rejection is respectfully requested.

Anticipation Rejection I

Claims 1-3, 8-10, 12, 14, 15, and 17-20 stand rejected on page 3 of the Office Action under 35 U.S.C. §102(b) over Zou (US 5,902,604). Claims 1-3, 8-12, and 14-20 stand rejected on page 4 of the Office Action under 35 U.S.C. §102(b) over Zou. Zou relates to submicron liposome suspensions obtained from preliposome lyophilizates.

In order for anticipation to exist, each and every feature as set forth in the claim must be disclosed in a single cited art document. *Trintec Industries, Inc., v. Top-U.S.A. Corp.*, 295 F.3d 1292, 63 U.S.P.Q.2D 1597 (Fed. Cir. 2002). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

Claim 1 recites "*a method of preparing solid nanometer medicines,* ***consisting of****: providing a solution with amphiphiles, wherein the amphiphile is* ***a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3****, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E, wherein the diameter of the solid particles ranges from 1 nm to about 300 nm.*"

Zou fails to disclose a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3. Zou discloses only a liposomal formulation using at least one lipid and a surfactant.

Moreover, Zou's preparing method involves forming a medicine solution (*e.g.*, Annamycin solution of DMSO) and then combining the medicine solution with a lipid solution in t-butyl alcohol/water. *See* column 9, lines 6-28 of Zou.

Contrary to Zou, in the subject invention, a medicine is directly added into a solution with amphiphiles; the medicine is NOT dissolved in a solvent prior to adding the medicine into the solution.

Consequently, Zou fails to disclose a method of preparing solid nanometer medicines, consisting of providing a solution with amphiphiles, wherein the amphiphile is a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E. Since Zou fails to disclose each and every feature of claim 1, Zou cannot anticipate claims 1-3, 8, 10, 12, 14, and 15. Accordingly, withdrawal of the rejection is respectfully requested.

Anticipation Rejection II

Claims 1-3, 8, 12, 14-15, and 17-20 stand rejected under 35 U.S.C. §102(b) over by Mehta (US 4,950,432). Mehta relates to a process for producing fine powder suitable for the preparation of liposome.

Mehta fails to disclose a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3.

Moreover, Mehta's preparing method involves dissolving a medicine (polyene macrolide) in a first organic solvent to form a first solution (a), removing the solvent to form a residue (c), dissolving the residue in a third organic solvent to form a third

solution (d), extracting the third organic solvent to leave a remnant (e), and forming a forth solution by dissolving the remnant in a solvent (f). *See* abstract and claims.

Contrary to Mehta, in the subject invention, a medicine is directly added into a solution with amphiphiles; the medicine is NOT dissolved in a solvent prior to adding the medicine into the solution.

Consequently, Mehta fails to disclose a method of preparing solid nanometer medicines, consisting of providing a solution with amphiphiles, wherein the amphiphile is a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E. Since Mehta fails to disclose each and every feature of claim 1, Mehta cannot anticipate claims 1-3, 8, 12, 14-15, and 17-20. Accordingly, withdrawal of the rejection is respectfully requested.

Anticipation Rejection III

Claims 1-4, 8, 9 11, 12, and 14-20 stand rejected under 35 U.S.C. §102(b) over WO 92/16196. WO '196 relates to a powdery preparation for intranasal administration of a physiologically active agent. The method of preparing the powder involves combining a) a lower alkyl ether of cellulose, b) a cyclodextrin or a derivative thereof, and c) a phospholipid. *See* Abstract. The lower alkyl ether of cellulose is used as an essential component.

The words "consisting of" in claim 1 disclaim using a lower alkyl ether of cellulose as an essential component. In fact, the words "consisting of" disclaim any act such as using a lower alkyl ether of cellulose as an essential component of WO '196. Thus, the claimed method of preparing solid nanometer medicines is different from WO '196's method.

Moreover, although WO '196 mentions a cyclodextrin, WO '196 does not disclose hydroxypropyl-beta-cyclodextrin as recited in claim 1.

Consequently, WO '196 fails to disclose a method of preparing solid nanometer medicines, consisting of providing a solution with amphiphiles, wherein the amphiphile is a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E. Since WO

'196 fails to disclose each and every feature of claim 1, WO '196 cannot anticipate claims 1-3, 8, 11, 12, and 14-16. Accordingly, withdrawal of the rejection is respectfully requested.

Anticipation Rejection IV

Claims 1-3, 7-9, and 12-21 stand rejected under 35 U.S.C. §102(b) over Zadi (US 2003/0138481). Zadi relates to a method for forming a liposome involving dissolving sugar into an aqueous suspension of liposome.

Zadi fails to disclose a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3.

Moreover, Zadi's method requires sugar an essential component. Zadi's method further requires using a preformed empty liposome containing liposome-forming compounds (lipids), which is prepared by a SUV formation process (co-dissolving the liposome forming compounds in chloroform, adding water followed by sonication, and centrifugation). *See* paragraphs [0040]-[0042] of Zadi. In addition, Zadi's requires an active ingredient in a particulate form, which requires a wet milling process, a precipitate process, or a colloid forming process. *See* paragraphs [0020]-[0021] of Zadi. Further, Zadi's method requires dehydrating and rehydrating. *See* Abstract of Zadi.

The words "consisting of" in claim 1 disclaim using sugar as an essential component. In fact, the words "consisting of" disclaim any act such as using sugar, a SUV formation process ,a wet milling process, colloid forming process, and the like of Zadi. Thus, the claimed method of preparing solid nanometer medicines is different from Zadi's method.

Consequently, Zadi fails to disclose a method of preparing solid nanometer medicines, consisting of providing a solution with amphiphiles, wherein the amphiphile is a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E. Since Zadi fails to disclose each and every feature of claim 1, Zadi cannot anticipate claims 1-3, 7, 8, and 12-16. Accordingly, withdrawal of the rejection is respectfully requested.

Obviousness Rejection I

Claims 5, 6, 8, and 12-15 stand rejected under 35 U.S.C. §103(a) over WO '196. As discussed above, WO '196 fails to teach or suggest all the features of claim 1. In particular, WO '196 fails to teach or suggest a method of preparing solid nanometer medicines, consisting of providing a solution with amphiphiles, wherein the amphiphile is a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E.

While the Office Action contends on page 5 that dissolution temperature of amphiphile and a size of particles have been obvious, WO '196 still involves the aforementioned deficiencies. Since WO '196 fails to teach or suggest all the features of claim 1, WO '196 cannot make claims 5, 6, 8, and 12-15 obvious. Accordingly, withdrawal of the rejection is respectfully requested.

Obviousness Rejection II

Claims 5, 6, 8, 13, and 21 stand rejected under 35 U.S.C. §103(a) over Zou. As discussed above, Zou fails to teach or suggest all the features of claim 1. In particular, Zou fails to teach or suggest a method of preparing solid nanometer medicines, consisting of providing a solution with amphiphiles, wherein the amphiphile is a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E.

While the Office Action contends on page 6 that dissolution temperature of amphiphile and the use of paclitaxel have been obvious, Zou still involves the aforementioned deficiencies. Since Zou fails to teach or suggest all the features of claim 1, Zou cannot make claims 5, 6, 8, and 13 obvious. Accordingly, withdrawal of the rejection is respectfully requested.

Obviousness Rejection III

Claims 9-11 stand under 35 U.S.C. §103(a) over WO '196 in view of Zou. As discussed above, both WO '196 and Zou fail to teach or suggest all the features of claim 1. In particular, WO '196 and Zou fail to teach or suggest a method of preparing solid nanometer medicines, consisting of providing a solution with amphiphiles,

wherein the amphiphile is a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E.

Consequently, the proposed combination of WO '196 and Zou fails to teach or suggest all the features of claim 1. Hence, the combination cannot make claims 10 and 11 obvious. Accordingly, withdrawal of the rejection is respectfully requested.

Obviousness Rejection IV

Claims 7 and 21 stand under 35 U.S.C. §103(a) over WO '196 in view of Zou. As discussed above, both Zou and Zadi fail to teach or suggest all the features of claim 1. In particular, Zou and Zadi fail to teach or suggest a method of preparing solid nanometer medicines, consisting of providing a solution with amphiphiles, wherein the amphiphile is a combination of hydroxypropyl-beta-cyclodextrin (HP-β-CD) and phospholipids at a weight ratio of 1 : 0.05 - 0.3, and the solution is selected from hydrophilic solvent, or a combination of hydrophilic solvent and water, and the claimed features B-E.

Consequently, the proposed combination of Zou and Zadi fails to teach or suggest all the features of claim 1. Hence, the combination cannot make claim 7 obvious. Accordingly, withdrawal of the rejection is respectfully requested.

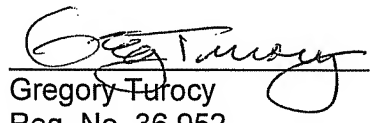
Petition for Extension of Time

A request for a one month extension of time is hereby made. Payment is being made through the EFS electronic filing system.

In the event any fees are due in connection with this document, the Commissioner is authorized to charge those fees to Deposit Account No. 50-1063.

Should the Examiner believe a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact applicants' undersigned representative at the telephone number below.

Respectfully submitted,
Turocy & Watson, LLP



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